Video Journal and Encyclopedia of GI Endoscopy (2014) 2, 79–83

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CLINICAL CASE REPORTS

Pancreatic Necrosectomy Through a Novel Double-flange Lumen-apposing Covered Metal Stent (Video)☆

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Received 15 June 2014; received in revised form 23 September 2014; accepted 15 October 2014

KEYWORDS
Pancreatic collection;
Pancreatic abscess;
Walled-off necrosis;
Necrosectomy;
Endoscopic ultrasound;
Covered metal stent;
Video

Abstract
Pancreatic fluid collections (PFCs) represent a complication of acute pancreatitis. Endoscopic management of PFCs is an alternative to surgery [1]. Classic strategies include access to the collection under endoscopic ultrasound (EUS)-guidance and placement of several double-pigtail stents. PFCs containing organized necrosis are classified as walled-off necrosis (WON). In those cases necrosis is hardly evacuated and will require necrosectomy in most cases. Every necrosectomy session needs prior removal of the stents, dilatation of the tract, debridement and placement of new stents adding up a considerable overall cost to the intervention. A novel double-flanged lumen-apposing fully-covered self-expandable metal stent (FC-SEMS) with a 15 mm diameter accelerates exit of the necrosis and facilitates multiple necrosectomy sessions. We present a 60 year old patient admitted to the intensive care unit for severe acute pancreatitis that developed WON with superinfection. The intensivists and surgeons indicated endoscopic cystgastrostomy to evacuate the collection. Using the echoendoscope we found a large collection adherent to the gastric wall. The collection was accessed under EUS-guidance using the Hot AXIOS™ catheter that features a cautery tip, then a 15 mm AXIOS™ stent was deployed through the cystgastrostomy orifice to keep it patent. The patient required two necrosectomy sessions to clean the cavity. The WON resolved in 6 weeks and the stent was removed unevently. The patient was discharged.

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http://dx.doi.org/10.1016/j.vjgien.2014.10.001

A double flange lumen apposing FC-SEMS used as a port for necrosectomy significantly improves management of walled-off pancreatic necrosis. Placement of this stents should be considered when multiple necrosectomy sessions are anticipated. Procedure time can be significantly decreased using a catheter that combines a cautery tip and stent delivery system.

Video related to this article

The video related to this article can be found online at http://dx.doi.org/10.1016/j.vjgien.2014.10.001.

1. Case report

- 60-years-old patient.
- Admitted to the ICU due to severe acute pancreatitis.
- During admission develops a 16 × 12 cm^2 walled-off pancreatic necrosis complicated with infection.
- Endoscopic ultrasound-guided cystgastrostomy with placement of a double flange lumen-apposing fully-covered self-expandable metal stent was performed.
- Two necrosectomy sessions were performed using the double flange lumen apposing FC-SEMS as a port to facilitate access to the cavity and extract the necrosis using nets.
- The collection resolved after 6 weeks and the stent was removed with a rat-tooth forceps.
- Six months after the procedure the patient was asymptomatic.

2. Materials

2.1. Cystgastrostomy and stent placement

- Echoendoscope (Olympus UCT-140, Olympus-Europe, Hamburg, Germany).
- Hot AXIOS™ 15-10 (Xlumena Inc., Mountain View, CA, USA).
  - Cautery tip
  - 10.8 Fr catheter
  - 15 × 10 mm^2 AXIOS™ stent pre-loaded.

2.2. Necrosectomy sessions

- Standard endoscope (Olympus GIF-H190, Olympus-Europe, Hamburg, Germany).
- Roth Net™ mini (US endoscopy, Mentor, OH, USA).

2.3. Stent removal

- Standard endoscope (Olympus GIF-H190, Olympus-Europe, Hamburg, Germany).
- Rat-tooth forceps (Olympus FG-8U-1, Olympus-Europe, Hamburg, Germany).

3. Endoscopic procedure

3.1. Cystgastrostomy creation and stent placement

- Study endosonographically the collection.
- Select an access point with fused walls if possible.
- The Hot AXIOS™ catheter is luer-locked to the working channel.
- Use Doppler to rule out the presence of vessels in the access path.
- Puncture the wall with the Hot AXIOS™ catheter using pure cut current 120 W (Figure 1A)
- Release the distal flange of the AXIOS™ stent under endosonographic view (Figure 1B).
- Switch to endoscopic view and check the Hot AXIOS™ catheter. Pull back the catheter until the black mark is seen.
- Release the proximal flange under endoscopic view.
- A large amount of fluid can exit the cavity at this point (Figure 1C). In those cases suction through the endoscope is recommended to prevent aspiration.

3.2. Necrosectomy sessions

- Insert an appropriate endoscope to access the collection through the AXIOS stent:
  - 15 mm AXIOS™: you can use a therapeutic, diagnostic or ultrathin endoscope.
  - 10 mm AXIOS™: you can use a diagnostic or ultrathin endoscope.
- Visualize the cystgastrostomy tract and the AXIOS™ stent.
- Access the cavity through the AXIOS™ stent using it as a port.
- Insert a net foreign body retriever (Figure 2A). Select the appropriate size based on the cavity characteristics, available space. In our case we used a Roth Net™ mini that is easier to maneuver into the cavity. It is possible to use other foreign body retrievers including baskets, snares, three-pronged grasping forceps.
- Remove as much necrosis as possible (Figure 2B). Take care not to damage the vessels that might be part of the walls.

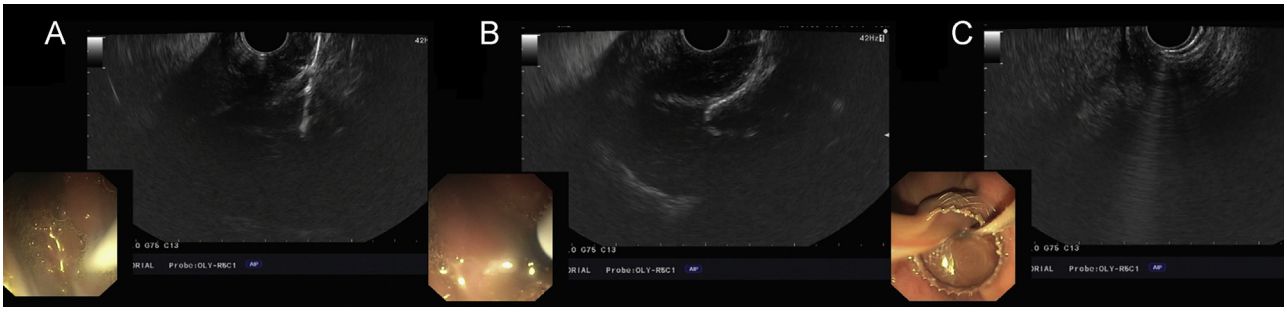

Figure 1 (A) Access with the cautery tip of the Hot AXIOS catheter under endosonographic guidance. (B) Deployment of the distal flange under EUS. The distal flange presents a characteristic echogenic mark resembling a mushroom. (C) Deployment of the proximal flange under endoscopic view. Pus flows through the stent.

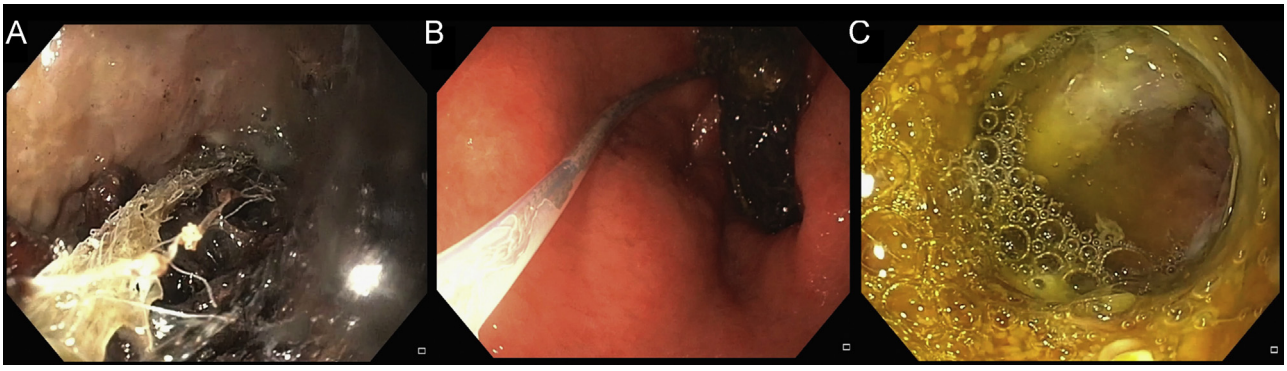

Figure 2 (A) Necrosectomy into the cavity using a net. (B) Pulling a large chunk of necrosis out of the cavity. Extraction might be difficult even through a 15 mm opening. (C) Upon resolution the walls of the cavity collapse blocking the distal flange of the stent.

3.3. AXIOS™ stent removal

- Insert an endoscope.
- Visualize the cystgastrostomy tract and the AXIOS™ stent.
- Access through the AXIOS™ stent using it as a port.
- Confirm that the cavity has resolved. This is seen as a wall in the distal end of the AXIOS™ stent (Figure 2C). The cavity should be inaccessible.
- Remove the stent using a rat tooth forceps.
  - The luminal flange of the AXIOS™ stent can be easily grasped with the forceps.
  - Close the forceps firmly, bring it close to the endoscope tip, lock the sheath to the working channel using your left hand.
  - Remove the stent pulling from the endoscope. A pop will be felt once the distal flange is removed.
  - The stent can be then taken outside and discarded.
- Another option would be to use a 25 mm or larger snare.

4. Discussion

Endoscopic ultrasound-guided transmural drainage of symptomatic pancreatic fluid collections is preferred to surgery or interventional radiology approaches [1]. Using double-pigtail plastic stents has been progressively substituted by the use of metal stents. Metal stents provide a larger opening improving drainage of walled-off necrosis. Initially stents with a tubular design were used. Those stents feature up to a 10% migration rate even if double-pigtail stents were used as anchors [2,3]. Modified FC-SEMS feature a double flange profile designed to allow lumen apposition thus decreasing the risk of pus leakage into the peritoneum. This design would allow treatment of non-adherent collections.

Most of those stents (AXIOS™, Xlumena Inc, Mountain View, CA; Nagi™, Taewoong Company, Seoul, Korea) require a two step procedure including access to the collection, insertion of a guidewire, exchange of the access device for the stent delivery catheter and deployment of the stent.

For our case we used a catheter that combines a cautery-tip for access and the AXIOS double-flange lumen-apposing FC-SEMS delivery system (Hot AXIOS™, Xlumena Inc., Mountain View, CA). This has demonstrated a significant decrease in procedure time down to 1 min approximately [4]. Cost of FC-SEMS is higher than that of plastic stents although there are no studies comparing overall procedure costs of both strategies. In cases requiring multiple necrosectomy insertions the cost of using multiple dilatation balloons, replacement of plastic stents, etc. could offset that higher cost but studies would be necessary to elucidate that point.

Double-flange lumen-apposing FC-SEMS provide a larger opening allowing its use as a port for necrosectomy and do not require anchoring stents [5]. Still, migration issues as well

as dislodgement of the stent during necrosectomy have been reported [6-8]. In some cases if the necrotic chunks are too large compared to the diameter of the stent (16 mm in the case of the Nagi™ and 15 mm in the case of AXIOS™) extraction may be difficult or impossible. In those cases dilatation of the stent or removal of the stent and dilatation of the orifice may be necessary [9].

5. Scripted voiceover

- Endoscopic management of pancreatic collections is an accepted alternative to surgery. Endoscopic ultrasound guided procedures represent the preferred approach lately.
- Classic steps include access to the collection, guidewire insertion, dilatation and placement of several double pigtail stents.
- The double -pigtail stents are inserted to keep the orifice patent and allow drainage of the collection.
- If large chunks of necrosis persist into the cavity, drainage can be unsuccessful and necrosectomy may be necessary.
- To clean the cavity, the stents need to be removed, the orifice dilated and necrosectomy has to be performed. New stents need to be placed.
- A novel double-flange lumen-apposing covered metal stent was recently presented.
- It is available in several diameters up to 15 mm. This stent acts as a port allowing passage of standard and therapeutic endoscopes.
- The Hot Axios device features a cautery tip in the stent delivery catheter allowing for access and stent deployment in a single step.
- The catheter is locked to the working channel of the echoendoscope. The catheter advance switch is unlocked prior to insertion. The distal flange is deployed under sonographic guidance. Once the black is visible endoscopically the proximal flange is ready to be deployed.
- A 60-years-old male was admitted to the ICU due to a large infected pancreatic collection.
- Here we can see the collection that measured up to 16 by 12 cm in the CT scan. Given the patient's condition, endoscopic drainage was indicated by the intensivists and surgeons.
- We decided to insert a 15 by 12 AXIOS stent using a Hot AXIOS catheter. Using a free hand technique the catheter is advanced into the collection using the cautery tip with pure cut current at 120 W.
- The distal flange is deployed under endosonographic guidance. The echogenic mark is typical.
- When we can see the black mark in the endoscopic image we begin deployment proximal flange. After deployment pus starts flowing out. The access and stent delivery maneuver took less than a minute.
- During the endoscopic follow-up the cavity is easily accessed through the stent. A cavity full of necrosis can be seen. A net is used to remove the necrosis. This is a tedious maneuver that has to be repeated several times. Care has to be taken not to damage vessels or other structures into the cavity. Large collections with extensive necrosis require several sessions for complete cleansing.
- At this time we find a large chunk of necrosis partially extruding through the stent. A 15 mm opening allows for spontaneous exit of the necrosis. In this case this is captured with a net. We had to exert a lot of pressure but could not remove easily the necrosis. Meaning that a larger chunk is still into the cavity. We begin to worry about the possibility of stent dislodgement. We can see that we have removed part of the chunk but still we need to exert more pressure and use different maneuvers to try to pull it out. Finally we could remove it. Here we can see the large chunk of necrosis after extraction.
- After extraction of the large chunk the cavity is almost clean. We use again the net to remove the remaining necrosis as we can see here.
- After 3 weeks the cavity is almost resolved.
- Follow up endoscopy reveals a clean cavity with granular tissue on the walls.
- After 6 weeks the collection has completely resolved. The stent is removed using a rat-tooth forceps. With pressure the stent pops out of place.
- A follow up CT scan confirms complete resolution of the collection.
- A double-flange lumen apposing covered metal stent can be used as a port for necrosectomy. This strategy significantly improves management of pancreatic collections with extensive necrosis. Placement of this stents should be considered when multiple necrosectomy sessions are anticipated. Procedure time can be significantly decreased using a cautery-tipped stent delivery catheter.

Ethics

All authors certify that this work described in our article has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans ⟨http://www.wma.net/en/30publications/10policies/b3/index.html⟩ and Uniform Requirements for manuscripts submitted to Biomedical Journals ⟨http://www.icmje.org⟩.

Conflict of interest

The authors have nothing to disclose and have no financial interests related to this manuscript.

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